PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:		10/595,977	Confirmation No.:	1136
Applicant	:	Mark Ashby	Filed:	June 14, 2007
Examiner	:	Mashack, Mark F.	TC/A.U.:	3773
Title	:	HEMOSTATIC PRESSURE PLUG		
Docket No.	:	1001.2219102	Customer No. :	28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By JoAnn Lindman

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

Appellants have carefully reviewed the Final Office Action mailed January 22, 2009 and the Advisory Action mailed March 30, 2009. Currently, claims 1, 27, 29-33, 40-49, 59, and 60 are pending in the application and claims 29-33 have been withdrawn. Claims 1, 27, 40-49, 59, and 60 have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1, 40-49, and 59-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Hannam et al. (U.S. Patent No. 5,649,959), herein after Hannam. Appellants respectfully traverse the rejection for at least the reason that all elements of the claims are not disclosed in Hannam. Hannam has been discussed in detail in the

earlier Pre-Appeal Brief submitted December 10, 2008 and the communication of March 18, 2009 filed in response to the new Final Office Action.

Hannam fails to provide a "release mechanism" which releases the flexible plug "at the blood vessel puncture site" as found in independent claim 1. In the final rejection of claim 1, the Examiner does not identify a release mechanism which releases the flexible plug, but rather notes "the release member comprises a suture **36** which would inherently be secured to the hemostatic body" (52). Hannam discloses that suture (36) is "fixedly or otherwise secured to the proximal side or surface of the anchor member 30" (Col. 7, lines 58-59.) The anchor of Hannam is secured to the filament and thus to the gelatinous material which engages the filament member as the gelatinous material dries or cures and thus cannot release the anchor. Severing the filament proximal of the gelatinous material would not release the anchor of Hannam. Indeed, a tensioned filament appears to be necessary to retain the anchor of Hannam adjacent to the puncture rather than allowing it to migrate within the vessel as it would if released. Tension is supplied to the filament of Hannam by external spring (68) which the Examiner has properly characterized as having that function in the Advisory Action. Hannam discloses "Next, the sheath 26 and tubular body 32 may be removed completely from the incision, and the portion of the filament member 36 extending beyond the skin of the patient may be cut leaving the incision sealed by the gelatinous material 52, anchor member 30 and filament member 36 as shown in FIG. 9." Figure 9, found on sheet 14 of the drawings indicates that the anchor has not been released in the vessel, although all insertion apparatus components have been removed, and the three remaining components are joined as a unit until they are eventually bioabsorbed. By contrast the flexible plug of pending claim 1 may be retained at the puncture site by differential pressure across the vessel wall following release of the plug within the vessel. Exemplary release mechanisms of claim 1 are illustrated in Figs. 3A-C and 6A-D and described at page 9, line 19 to page 10, line 10 and 12, line 20 to page 14, line 2, each of which sever a connection to the plug in the vicinity of the puncture and within the tissue tract (52). Even in those embodiments in which the release mechanism is a coupling releasing the plug at the puncture site, it is decoupled well within the tract rather than being allowed to extend beyond the skin as disclosed in Hannam.

The Examiner has applied the term "release mechanism" to the resilient extension member or spring (68) in rejecting claims 44-49 and 59-60 which depend from independent claim 40 and add significant limitations thereto. A release mechanism does not appear in independent claim 40. In the Advisory Action mailed March 30, 2009, the Examiner quotes Hannam as disclosing that 'spring member 62 is to "retain the anchor member 30 in a desired position adjacent to the wall of the artery" (Column 11, lines 16-19'. As noted above, spring (68) serves only to maintain tension on filament member (36) and so cannot be said to provide a release mechanism even in dependent claims. It is difficult to understand how a member which retains the anchor by applying tension to it may be considered to constitute a release mechanism. At no time does the spring (68) appear to release the anchor.

Independent claims 1 and 40 require a flexible plug "sized to circumferentially cover the blood vessel puncture site". Further, the plug conforms to and seals the blood vessel puncture site under the influence of a pressure differential between the interior and exterior of the vessel in the manner of a flexible sheet covering the drain of a sink. Once positioned, the flexible plug may be released within the blood vessel where it will be held in place by the differential pressure.

Appellants have cited column 7, lines 25-40 of Hannam as indicative of the form and characteristics of the anchor disclosed by Hannam. In that passage, the anchor is described as "a relatively thin, narrow strip of material" which aligns generally parallel to the artery an has a length and stiffness great enough to prevent it from being drawn back through the puncture site when tension is applied to filament member (36) as required for the further operation of the assembly. Hannam does not use the terms disk, circle, patch, or the like to describe the anchor. Accordingly, the anchor of Hannam neither covers the puncture circumferentially, or in the form of a disk, nor does it seal the puncture. The Examiner has cited column 7, lines 41-54 of Hannam which describes a variation of the anchor of Hannam which unfolds or expands once inserted within the vessel and asserts that the passage discloses "an apparatus comprising: a flexible disk (30) being sized to circumferentially cover the blood vessel puncture site and seal the blood vessel puncture". Although the cited passage suggests that the anchor may be folded or compressed in order to fit within the tubular body (32) for delivery into the vessel,

nothing suggests that its form, when deployed, is anything other than the thin, narrow strip described earlier and found in the figures. There is no indication that Hannam discloses a flexible disk to seal the vessel puncture site as found in claim 40 or that the plug is sized to circumferentially cover the blood vessel puncture site and to seal the blood vessel puncture site. Instead element (30) of Hannam serves to anchor the filament about which the sealing means is disposed. See column 4, lines 9-22:

> The closure assembly of the present invention preferably generally includes an anchor member, a gelatinous or similar material which forms a sealing means, and a filament member. The anchor member includes a tissue engaging portion and is configured to pass through the opening in one direction, but is resistant to passage therethrough in the opposite direction. The sealing means includes a gelatinous material, such as a tissue glue, including a cyanoacrylate, or fibrin material which engages the filament member as the gelatinous material dries or cures. The filament member is an elongate member that is preferably formed of a suture material having a length which is sufficient to be connected between the anchor member and the sealing means while extending across the wall of the vessel, duct or lumen. (Emphasis added.)

Sealing is provided by the gelatinous sealing means. The only properties attributed to the anchor relate to its anchoring functions, namely that it is configured to pass into the vessel and to resist removal. Although the anchor may partially obstruct the puncture and is said to "close off the puncture", Hannam explicitly relies upon a separate sealing means external to the vessel to stop blood flow from the vessel. Hannam explicitly notes that: "Additionally, the clot formed by the gelatinous material 52 will absorb any bleeding from the tissue surrounding the incision 28 and will also absorb any blood which may seep past the anchor member 30." indicating that Hannam is aware that his anchor does not provide an effective seal. (Col. 12, lines 35-39)

Further, in the Advisory Action, the Examiner attempts to refute Appellants' argument that "Plunger (38) does not couple a hemostatic body to the flexible disk at all." by referring to Figures 3 and 4 and col. 10, lines 31-33. This issue was raised when the Examiner asserted in the final Office Action that plunger (38) "couples the flexible disk to the hemostatic body and is smaller than the disk and hemostatic body". In the cited figures, hemostatic body (52) is not yet present and plunger (38) is not coupled to either anchor (30) or filament (36). The plunger serves only to eject the anchor from outlet (34)

within the vessel. (See the cited passage.) This becomes apparent when the plunger is completely withdrawn between Figs. 6 and 7 leaving the anchor and attached filament in place. The hemostatic body, corresponding to gelatinous material (52) is then introduced by syringe assembly (33) which replaces plunger (38).

For at least these reasons, Hannam does not disclose each and every element in as great detail as set forth in independent claims 1 and 40. Appellants believe that claims 1 and 40 are patentable over Hannam and request that the Examiner's rejections be overruled. Further, claims 41-49, and 59-60 depend from, and add further limitations to, claim 40 and Appellants request that those rejections be overruled.

With respect to claim 27 which was rejected under 35 U.S.C. 102(b) over Hannam or in the alternative under 35 U.S.C. 103(a) over Hannam in view of Haaga (U.S. Patent No. 5,254,105). Claim 27 depends from independent claim 1 and adds significant limitations thereto and Appellants request that the Examiner's rejection under 35 U.S.C. 102(b) be overruled. In the alternative, Appellants note that Haaga is said to teach "of a vascular surgical device comprising a hemostatic material encapsulated in a biocompatible dissolvable capsule". This teaching does not overcome the deficiencies of Hannam with respect to claim 1, as discussed above, from which claim 27 depends and to which it adds additional limitations. Accordingly independent claim 1 is nonobvious over Hannam in view of Haaga and claim 27, which depends from nonobvious claim 1, is also nonobvious. (MPEP 2143.03) Appellants respectfully request that the rejection of claim 27 under 103(a) be overruled.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: April 21, 2005

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